IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC
PELVIC REPAIR SYSTEM,
PRODUCTS LIABILITY LITIGATION MDL NO. 2327

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THIS DOCUMENT RELATES TO ALL CASES

NOTICE TO TAKE ORAL DEPOSITION
OF DEFENDANT ETHICON LLC THROUGH DESIGNATED WITNESSES

TO: Defendant ETHICON, LLC and its Attorneys of Record.

Please take notice that pursuant to Rule 30(b)(6) of the Federal Rules of Civil Procedure, Plaintiffs, by and through their counsel, will take the videotaped deposition of a designated witness of Defendant Ethicon, LLC at an agreed upon date and location. The witness(es) shall be prepared to testify concerning the subject matter identified in Exhibit "A", attached hereto. The witness shall produce documents identified in Exhibit "B", attached hereto, prior to the deposition. The deposition will be taken before a person authorized by law to administer oaths, pursuant to Rule 28 of the Federal Rules of Civil Procedure, and will continue day-to-day until the examination is completed.

DEFINITIONS

All definitions and rules of instructions set forth in Fed. Rule Civ. P. 30(b)(6) shall apply to all requests for information herein. To the extent a term commonly in use in the medical device industry is not defined herein, it shall be understood to be consistent with the meaning commonly ascribed to that term in the medical device industry.

1. "Concerning" means referring to, describing, evidencing, or constituting. See LR Civ. P 26.2(c)(7).

2. "Defendant", "Ethicon, LLC", "you" or "your" refers to, without limitation,

Ethicon, LLC and all business entities with which it is or has been affiliated, together with any predecessor, successor, parent, or subsidiary entity as well as any officer, director, employee, attorney, agent, or representative of any such other business entity previously described herein.

3. "Document" is synonymous in meaning and equal in scope to the usage of this term in Rule 34(a) of the Federal Rules of Civil Procedure and expressly includes writings, drawings, graphs, charts, photographs, sound recordings, images, and other data or data compilations stored in any medium from which information can be obtained either directly or, if necessary, after translation by you into a reasonably usable form. A draft or non-identical copy is a separate document. *See* LR Civ. P. 26.2(c)(2); *see also* FR Civ. P 34(a).

4. "Mesh Product" means any product that you developed, designed, distributed, licensed, manufactured, marketed or sold for the treatment of Pelvic Organ Prolapse (POP) or Stress Urinary Incontinence (SUI).

5. "Relevant Time Period" means the time period from when you first developed, designed, distributed, licensed, manufactured, marketed or sold pelvic mesh products to the present.

PLAINTIFFS' CO-LEAD COUNSEL

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EXHIBIT "A"

DEPOSITION SUBJECT MATTER

Pursuant to Rule 30(b)(6), the deponent(s) must have knowledge and shall be able to testify concerning the following subject matters:

I. COMPANY STRUCTURE AND ORGANIZATION

1. Ethicon, LLC's parent, subsidiary and affiliate companies involved with the development of its pelvic mesh products.

2. Ethicon, LLC's company structure and organization, and more specifically:

   a. The internal organizational structure of Ethicon, LLC's individual departments, groups, regions, divisions, committees and/or task forces;

   b. The organizational structure within each of Ethicon LLC's departments, groups, regions, divisions, committees and/or task forces, including the identity of the individuals who performed work related to your pelvic mesh products;

   c. All persons, organizations, departments, entities, committees and/or task forces involved in the research, development, production, regulatory compliance, testing, packaging, distribution, sanitization, manufacturing and quality control of Ethicon LLC's pelvic mesh products; and

   d. The functions, duties and responsibilities of each department, group, region, division, committees and/or task forces related to the development, manufacturing and testing of or work with your pelvic mesh products.

3. The nature, location, storage and organization of all documents and electronically stored information related to any meetings or activities of Ethicon LLC's boards of directors and/or board of director committees and subcommittees, including but not limited to meeting minutes, reports, handouts and investigational documents from the date Ethicon, LLC first started researching, manufacturing, and/or developing its pelvic mesh products until the present.

4. The organizational (whether direct or indirect), operational and contractual relationships, if any, between Ethicon, LLC and Johnson & Johnson; and Ethicon LLC and Ethicon Inc. (or any of their respective shareholders, members, partners or equity owners).

5. All persons, organizations, departments, entities, committees and/or task forces involved in the research, development, manufacturing and production of Ethicon LLC's pelvic mesh products.

6. The structure of any working or functional department or group, including the identity of those individuals working therein, responsible for announcing, overseeing, carrying out and/or effectuating the market withdrawal of any of your pelvic mesh products.

7. The structure of any working or functional department or group, including the identity of those individuals responsible for interacting with any in-house or third party contractors or companies related to the manufacture of your pelvic mesh products, including any changes over time, and the contractual relationship(s) with those third parties.

8. The structure of any working or functional department or group, committee, and/or task force including the identity of those individuals responsible for tracking, recording, reporting, handling, following up on complaints, problems, and adverse event reports relating to your pelvic mesh products.

II. MANUFACTURING AND DISTRIBUTION PRACTICES

1. The following manufacturing/distribution topics and the identity of all persons within Ethicon, LLC and all committees, groups, departments, and/or boards and the like (including their names, responsibilities, dates of operation and the identity of their members), who/which were responsible at any and all time periods for the following from the date Ethicon, LLC first started manufacturing and distributing its pelvic mesh products until the present:

a. Sterilization and sanitization of the product, plant and equipment used in the manufacture of the pelvic mesh products, including those responsible for developing policies and procedures regarding sterilization and sanitization and those responsible for ensuring compliance with those policies and procedures;

b. The maintenance of records regarding the sterilization and sanitization of the product, plant and equipment used in the manufacture of the pelvic mesh products, including maintaining and updating policies and procedures regarding sterilization and sanitization;

c. Inspecting, measuring, testing, and otherwise ensuring compliance with specifications for finished products;

d. Inspecting, measuring, testing, and otherwise ensuring compliance with specifications for product components;

e. Inspecting, measuring, testing, and otherwise ensuring compliance with specifications for product raw materials;

f. End-to-end production process for Mesh Products, including extrusion of continuous filament, winding, knitting, scouring, and/or annealing;

g. Inspecting finished mesh products for surface effects and/or variations in the finished products;

h. Measuring process variables, including temperature effects at the extrusion die, water content of the polymer, the finish of the tool and/or residual process materials that have not been completely removed through scouring;

i. Measuring polypropylene variables, including tacticity, presence of extrusion processing aids, monomers, dimers and/or residual catalyst;

j. Implementing and maintaining any manufacturing and distribution process tracking technologies employed by Ethicon LLC, including but not limited to technologies such as RFID and barcodes and the means of collection, retention and integration of these data through the product lifecycle;

k. Installing, inspecting, maintaining, and operating equipment used to produce pelvic mesh products, including, but not limited to laser cutting equipment and mechanical cutting equipment used in the production of pelvic mesh;

l. The substantive preparation, printing, and placement of package inserts, product packaging, IFUs and other labeling for your pelvic mesh products (both U.S. and foreign), including the specific dates of use for each such items and any changes thereto;

m. The substantive preparation and approval of any manufacturing process changes regarding your pelvic mesh products, including the specific dates and reasons for each change;

n. The investigation, evaluation and determination as to whether there is an association between manufacturing defects/problems/errors related to your pelvic mesh products and any adverse event experienced by patients who were provided your pelvic mesh products;

o. The investigation, evaluation and determination as to whether there is a causal connection between your pelvic mesh products and any adverse event or injuries;

p. Personal injury litigation concerning your pelvic mesh products;

q. The maintenance of Ethicon LLC's finances, budgets and expenditures related to its pelvic mesh products from the date first started developing and manufacturing its pelvic mesh products until the present;

r. The interaction and communication internally or with any outside consultants regarding the manufacturing, engineering, distribution, safety, or compliance of your pelvic mesh products, from the date Ethicon, LLC first started developing and manufacturing pelvic mesh products until the present;

s. The Corrective and Preventative Action Plan ("CAPA") relating to failure to properly maintain documents necessary for regulatory or litigation purposes;

t. The Corrective and Preventative Action Plan ("CAPA") relating to failure of Prolene Mesh not being packaged (folded) as specified in the Process Specification for Packaging of Mesh Product;

u. The Corrective and Preventative Action Plan ("CAPA") relating to Gynemesh non-absorbable Prolene Soft mesh not being properly sealed as well as evaluating units for packaging integrity;

v. The Corrective and Preventative Action Plan ("CAPA") related to the increase in complaints with the TVT-Secur in Australia reported by Dr. Aran Maree.

w. The Corrective and Preventative Action Plan ("CAPA") related to defective inserter springs in the TVT-Secur.

x. Documentation of Investigations of causes of nonconformities and corrective and preventative actions ("CAPA");

y. The auditing of the conduct of the company and its officers and employees in connection with the development, design, manufacture, distribution, testing and quality assurance of pelvic mesh products from the date Ethicon, LLC first started developing pelvic mesh products until the present;

z. The firm's quality manual, quality policy, written procedures for management review, quality audits and quality plan and management review of the same;

aa. Manufacturing standards for space between pores of pelvic mesh products as well as evaluation and testing of the space between pores;

bb. Rejected Product that did not meet product specifications as well as the destruction or disposal of such product including records of the product;

III. OUTSIDE CONTRACTORS/CONSULTANTS

1. All persons or entities that Ethicon, LLC (including the name, employer or the corporate entity the person is associated with, the time period in which the relationship existed, the title, role, function of the individual or entity, and a general description of the nature of the consultation or discussion) consulted with or retained concerning your pelvic mesh products from the date Ethicon, LLC first started developing pelvic mesh products until the present. Areas of inquiry related to the identity of these consultants will include but will not be limited to the following:

a. Ensuring and/or evaluating compliance with laws and regulations regarding product manufacturing;

b. Ensuring and or evaluating compliance with quality manufacturing procedures and policies, included but not limited to auditing of procedures such as ISO 9000 and any similar procedures;

c. Involved in responding to any perceived deficiencies to Ethicon LLC's processes or manufacturing, including Corrective and Preventative Actions, (CAPA's) Product Quality Issues (PQI's) as well as any similar issues;

d. Testing, maintenance, repair, setup and operation of Plant equipment;

e. Scientific, Manufacturing, and Engineering consultants;

f. Product testing;

g. Machine Testing;

2. Ethicon LLC's third party consultants or entities retained for Manufacturing, Engineering, Product Testing, Auditing, and the nature of the work done by those consultants and the time periods during which they were retained from the date Ethicon LLC first started developing pelvic mesh products until the present.

IV. REGULATORY

1. The company organization and structure of Ethicon, LLC relating to the approval, management, administration, operation and compliance with any and all U.S. medical device regulations applicable to your pelvic mesh products from the date Ethicon LLC first started developing pelvic mesh products until the present.

2. The company organization and structure of Ethicon LLC relating to the approval, management, administration, operation and compliance with any and all foreign medical device regulations applicable to your pelvic mesh products from the date Ethicon LLC first started developing pelvic mesh products until the present.

3. Ethicon LLC's company officers and other employees (including but not limited to their titles, duties and dates of such responsibility) who were and are responsible for communicating with regulatory officials with the FDA and related regulatory bodies concerning

regulatory approval and compliance with U.S. medical device regulations concerning your pelvic mesh products from the date Ethicon LLC first started developing pelvic mesh products until the present.

4. Ethicon LLC's company officers and other employees (including but not limited to their titles, duties and dates of such responsibility) who were and are responsible for communicating with domestic and foreign regulatory bodies about your pelvic mesh products from the date Ethicon LLC first started developing pelvic mesh products until the present.

5. The organization charts and structure of all Ethicon, LLC employees relating to the pelvic mesh products from the date Ethicon LLC first started developing pelvic mesh products until the present.

6. Ethicon LLC's practices and procedures for the review, submission and approval concerning its pelvic mesh products relating to the following regulatory provisions:

a. Labeling, contraindications and adverse event warnings;

b. Post-marketing reporting and warnings; and

c. The intake, investigation, processing, handling and reporting to the FDA and other governmental regulatory bodies of all adverse event reports.

7. The location, storage and organization of any and all documents that relate to U.S. and foreign regulatory affairs and matters concerning Ethicon LLC's pelvic mesh products, including but not limited to regulatory communications, interchanges between Ethicon LLC's personnel and any regulatory body or personnel, memoranda, electronic data, working drafts, regulatory guidance documents, internal writings, communications to and from Ethicon LLC personnel regarding regulatory matters, labeling records, drafts of labeling records, minutes of meetings with regulatory personnel, regulatory contact reports or sheets, Investigational device submissions, 510(k) submissions, Safety Update Reports, and any and all other documents which

in any way relate to regulatory affairs applicable to your pelvic mesh products from the date Ethicon LLC first started developing pelvic mesh products until the present.

8. Communications between Ethicon LLC and the FDA regarding the manufacturing, marketing, sale, promotion or advertising of pelvic mesh products.

V. ADVERSE EVENT REPORTING

1. Communications between Ethicon LLC and the FDA as well as communications between Ethicon LLC and any other Ethicon entities concerning the review, analysis and summaries of post-marketing adverse event reports regarding its pelvic mesh products.

2. The processes and procedures used by Ethicon, LLC in connection with processing of adverse event reports, including the identification of policy manuals, SOPs, and safety or pharmacovigilance manuals.

3. The procedures for the intake, processing, handling, analyzing, investigating and reporting to the FDA and to any other U.S. governmental bodies reports of adverse events concerning your pelvic mesh products.

4. The processes and procedures by which Ethicon, LLC receives and processes clinical trial adverse events from its clinical trials, including the processes by which Ethicon, LLC conducts follow-up investigations on adverse event reports from its clinical trials or post marketing surveillance.

5. The processes and procedures by which a determination is made by Ethicon, LLC as to whether an adverse event should or should not be found to be related to one of its pelvic mesh products.

6. All databases that contain adverse event reports from any source.

7. The existence, maintenance, and location of records of all contacts with the FDA or communications between Ethicon, LLC and the FDA related to adverse event reports, adverse event reporting, pharmacovigilance, or postmarketing surveillance.

8. The process and procedures for storing, testing and/or analyzing pelvic mesh products that have been returned to Ethicon, LLC due to complaints of malfunction or complications and the location of any and all such storage facilities

VI. LABELS – U.S. AND FOREIGN

1. The creation, drafting, revision, submission, negotiation, approval, printing, translation, identity and distribution of all U.S. and foreign pelvic mesh product package IFU/labels, including but not limited to the following:

a. The substance of each package IFU/label and any changes thereto;

b. The authorizations for making each change to the IFU/label;

c. The date each IFU/Label change received any and all approvals (both within Ethicon LLC and by the FDA or regulatory agency) necessary to make each change;

d. The dates each new IFU/Label actually began being disseminated publicly and placed within new packages of pelvic mesh products by Ethicon LLC;

EXHIBIT "B"

DOCUMENT REQUESTS

Please produce:

1. All documents relied upon by the deponent in preparing for this deposition.

2. All documents concerning company, departmental, and employee organizational charts.

3. All protocols or standard operating procedures (SOP) for:

   a. Your regulatory department;
   b. Your safety department (including medical device reporting);
   c. Your post-market surveillance department;
   d. Your risk management department;
   e. Your quality assurance department;
   f. Manufacturing of your mesh products.

4. All documents reflecting correspondence between the FDA and Ethicon LLC regarding pelvic mesh products or facilities and procedures involved in the manufacture of pelvic mesh products.

5. All current and former product specifications for pelvic mesh products including draft copies.

6. The firm's quality manual, quality policy, written procedures for management review, quality audits and quality plan as well as minutes and notes management review meetings regarding these documents.

7. Any documents indicating or discussing deviation from product specifications, including but not limited to, fraying, bunching, curling, degradation, fading, crumbling, folding, toxicity or sizing of mesh.

8. Records of product that was rejected and destroyed or otherwise disposed for not meeting product specifications.